**ANNEXURE.13.**

**Format for submission of Annual Progress Report for investigators**

*Kindly Send a soft copy also on* *iec.igmc.sml@gmail.com* *for easy redressal*

**1. Principal Investigator details**

1. Name
2. Designation
3. Department
4. Email ID
5. Contact number

**2. Study details-**

1. Title
2. IEC Number
3. IEC Approval date
4. Sponsor / Grant agency
5. CTRI number (in case of Clinical Trial):

If not registered, give reason

1. Date of start of study

(if not started, give reason and expected start date)

1. Date of last status report (if submitted)

**3. Summary of work done (**along with preliminary findings and

 publications from research if any)

1. Till date
2. Within last one year

**4. Serious Adverse Events (SAEs)** /**any unexpected adverse event**

 Were all SAEs/ unexpected adverse event reported to IEC

1. If yes, reference number and dates
2. (if no, give reason)

5. Whether reports of SAEs at other sites have been submitted

 to the IEC IGMC Shimla.

**6. Protocol amendments within last one year (if any)**

1. Were these amendments approved by the IEC
2. (if no, give reason)

**7. Protocol violations within last one year**

 Any major protocol violations (if any)

1. If yes, were they reported to IEC (reference number and dates)
2. (if no, give reason)

8. **New information**

 Any new information that can alter the risk/benefit assessment

 (If yes, give details)

**9. Other issues within the last 1 year**

 Any issues that PI wishes to report to IEC

 (change of Co-I, addition/deletion of sites, etc.)

 If yes, give details

10. **Signature of PI with date**